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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,181	11/16/2001	Avi J. Ashkenazi	P2730P1C53	3268

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EXAMINER

KEMMERER, ELIZABETH

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/991,181

Applicant(s)

ASHKENAZI ET AL.

Examiner

Elizabeth C. Kemmerer, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 119-126, 129-131 and 135-145 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 119-126 and 135-145 is/are rejected.
- 7) ☒ Claim(s) 129-131 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/22/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

The amendment received 22 June 2004 has been entered in full. Claims 1-118, 127, 128 and 132-134 are canceled. Claims 119-126, 129-131 and 135-145 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The objection to the disclosure regarding improper use of hyperlinks as set forth at p. 2 of the previous Office Action (mailed 22 March 2004) is *withdrawn* in view of the amendments (amendment received 22 June 2004).

The rejection of claim 131 under 35 U.S.C. § 112, first paragraph, regarding enablement of a biological deposit, as set forth at pp. 3-4 of the previous Office Action (mailed 22 March 2004) is *withdrawn* in view of the amendments (amendment received 22 June 2004).

The rejection of claims 119-124, 127, 128 and 132-138 under 35 U.S.C. § 112, second paragraph, as set forth at p. 11 of the previous Office Action (mailed 22 March 2004) is *withdrawn* in view of the amended claims (amendment received 22 June 2004).

The rejection of claims 132-134 under 35 U.S.C. § 102(b) as being anticipated by Zenno et al. as set forth at p. 12 of the previous Office Action (mailed 22 March 2004) is *withdrawn* in view of the amended claims (amendment received 22 June 2004).

35 U.S.C. § 112, First Paragraph

Claims 119-126 and 135-145 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated nucleic acids, vectors and host cells comprising an isolated nucleic acid comprising the full-length coding sequence of the nucleic acid sequence of SEQ ID NO: 193 or the full-length coding sequence of the cDNA deposited under ATCC accession number 209977, does not reasonably provide enablement for any nucleic acid variants thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The basis for this rejection is set forth at pp. 5-8 of the previous Office Action (mailed 22 March 2004).

Applicant's arguments (pp. 10-12, amendment received 22 June 2004) have been fully considered but are not found to be persuasive for the following reasons.

Applicant argues that the rejection has been obviated in part by the amendment to the claims requiring the claimed nucleic acids to be amplified in colon tumors. This has been fully considered but is not found to be persuasive. The amendment to the claims reciting that the claimed nucleic acids are amplified in colon tumors does not obviate the rejection. Only the full-length coding region of SEQ ID NO: 193 has been shown to be amplified in colon tumors. The specification provides no guidance nor working examples directed to variants of the full-length coding region of SEQ ID NO: 193 which also can be used as probes to show amplification of the PRO1009 gene in

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colon tumors. One skilled in the art could not predict what types of modifications or extent of modification of the full-length coding sequence of SEQ ID NO: 193 could be made without destroying the probe's specificity without resorting to trial and error experimentation for each variant sequence. Also, the breadth of the claims is quite large, given that the claimed nucleic acid need only have 85% identity to any degenerate nucleic acid encoding SEQ ID NO: 194, for example (see claim 120). The encompassed nucleic acids could have much lower percent identity to SEQ ID NO: 193. Upon consideration of all of these factors, undue experimentation would be required of the skilled artisan to make and use the claimed invention in its full scope.

Applicant also disagrees with the rejection's statement that increases in gene copy number do not reliably correlate with increased gene expression or polypeptide expression, but point out that this issue is irrelevant to the claims which are not directed to polypeptides or other products of gene expression. Applicant asserts that reliance on Pennica, Konopka and Haynes is improper. Applicant argues that the specification teaches how to make nucleic acid variants, and that one skilled in the art would know how to make and use these variants for diagnosis of colon cancers without undue experimentation. This has been fully considered but is not found to be persuasive. The Pennica, Konopka and Haynes references were relied upon to address the assertion in the specification that variant nucleic acids could be used to make polypeptides which could also be used as colon cancer diagnostics. However, as explained in the previous Office Action, one skilled in the art would not assume that the gene products of PRO1009 could be used in cancer diagnostics without extensive further testing.

Due to the large quantity of experimentation necessary to determine how to use fragments and variants of an isolated nucleic acid comprising the full-length coding sequence of the nucleic acid sequence shown in Figure 122 (SEQ ID NO: 193) or the full-length coding sequence of the cDNA deposited under ATCC accession number 209977, the lack of direction/guidance presented in the specification regarding such fragments and variants, the absence of working examples directed to fragments and variants, the complex nature of the invention, the state of the prior art showing that gene amplification data do not necessarily extend to variants that encode the same or similar proteins, the unpredictability of the effects of mutation on probe specificity, and the breadth of the claims, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claims 119-126 and 135-145 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is set forth at pp. 9-10 of the previous Office Action (mailed 22 March 2004).

Applicant's arguments (pp. 12-13, amendment received 22 June 2004) have been fully considered but are not found to be persuasive for the following reasons.

Applicant reviews the legal standard for written description, with which the examiner takes no issue.

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Applicant argues that, based on the detailed description of the cloning and expression of variants of PRO1009 in the specification, the description of the gene amplification assay and description of testing the ability of test variant polypeptides in the assay, the actual reduction to practice of sequence SEQ ID NO: 194 and 193 and the functional recitation in the instant claims, Applicants submit that one of skilled in the art would know that Applicants possessed the invention as claimed in the instant claims. This has been fully considered but is not found to be persuasive. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In the instant case, only one nucleic acid sequence has been identified with a link to cancer as recited in the claims. No other species have been disclosed. One species is not adequately representative of the many sequences encompassed by the claims.

Claim Objections

Claims 129-131 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant argues (p. 14, amendment received 22 June 2004) that the objection to the claims has been overcome since claim 124, upon which the claims depend, is

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believed to be allowable. This has been fully considered but is not found to be persuasive, because claim 124 is not allowable for reasons discussed above.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Thursday, 7:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, Ph.D. can be reached on (571) 272-0961. The fax

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phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ECK

A handwritten signature in cursive script that reads "Elizabeth C. Kemmerer".

ELIZABETH KEMMERER
PRIMARY EXAMINER